UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

NOVOTECH (AUSTRALIA) PTY LIMITED, an Australian proprietary limited company, Plaintiff, v. SURECLINICAL, INC., a Nevada corporation, Defendant.	No. 2:22-cv-01259 JAM AC ORDER

This matter is before the court SureClinical's motion to (1) compel Novotech to grant SureClinical's auditor direct access to Novotech's business records for the purpose of completing the audit provided for in the parties' contract and previously ordered by this court; (2) compel Novotech to further grant access and cooperate in a forensic examination of its electronic systems and devices and media to the maximum extent necessary for a forensic examiner selected by SureClinical to determine whether or not Novotech has destroyed, altered, or concealed records or information (including electronically-stored information and metadata) responsive or related to the audit; (3) for the magistrate judge to certify facts to the District Court in accordance with 28 U.S.C. § 636(e) for further proceedings to determine whether an Order to Show Cause shall issue as to why Novotech should not be held in contempt and sanctioned for noncompliance with this

Court's December 5, 2022 and January 20, 2023 Orders; and (4) award SureClinical its costs and attorney fees incurred to bring its Motion to Compel and this Renewed Motion. This matter was referred to the assigned Magistrate Judge pursuant to the order of the District Judge. ECF No. 45. The parties filed a joint statement, ECF No. 55, and appeared for oral argument on July 19, 2023, ECF No. 57. For the reasons stated below, the motion is granted in part and denied in part.

I. Relevant Background

SureClinical is the developer of a cloud-based software platform used to facilitate clinical research trials in the biotechnology and pharmaceutical industries. ECF No. 55 at 8. Novotech is a clinical research organization ("CRO") that manages clinical research trials for its biotechnology and pharmaceutical company clients. Id. In 2014, SureClinical and Novotech entered into the Master Subscription Agreement ("MSA") at issue in this action. See Phillips Decl. (ECF No. 55-1), Ex. 1 (MSA); Holloway Decl. (ECF No. 55-3) Ex. 1 (same). The MSA, which expired by its terms on December 31, 2022, granted Novotech a license to use SureClinical's platform ("Platform"). Id. at § 2.4. The parties dispute the scope of the license. ECF No. 55 at 8.

The MSA includes an "Audit Rights" provision, which states, in pertinent part:

> You [Novotech] agree to keep, maintain and preserve full and accurate accounts and records of all use of the Service, examination of which would enable SureClinical to confirm your compliance with Section 2.4 (Restrictions) of this Agreement during the Term. At any time while a subscription is in effect and for two years after termination of the subscription, SureClinical shall have the right to audit Your records to confirm Your compliance with Section 2.4 (Restrictions) of this Agreement. SureClinical shall initiate such audit by notifying You in writing of its intention to conduct an audit of Subscriber's records ("Audit Notice"), and You shall make the requested records available for inspection as soon as reasonably practicable, which in no event shall exceed ten (10) business days from the date of SureClinical's Audit Notice. . . You shall provide to the auditors such supplementary information and explanation reasonably necessary to explain fully the information contained in Your books, records and accounts.

MSA § 11.8; see also ECF 30 at 8:19-24 ("Under the plain terms of section 11.8, SureClinical has the right to audit Novotech's records to ensure Novotech's compliance with the MSA's restrictions and Novotech is required to make requested records available for inspection by the

auditor no later than ten days after receipt of SureClinical's audit notice.").

Section 2.4 of the MSA provides in pertinent part:

> [Novotech's] access to the Services is provided to [Novotech] on the condition that [Novotech] do[es] not (and do[es] not allow any third party to) modify, distribute, prepare derivative works of, reverse engineer, reverse assemble, disassemble, or decompile the Services, any object code generated by the Services or any part thereof, or otherwise attempt to discover any source code, modify the Services in any manner or form, or sue unauthorized or modified versions of the Services, including (without limitation) for the purposes of building a similar or competitive product or service or for the purpose of obtaining unauthorized access to the Services . . .

MSA § 2.4.

On July 14, 2022, SureClinical's auditor, the accounting firm Miller Kaplan Arase LLP ("Miller Kaplan" or "MKA"), sent Novotech a letter stating that SureClinical intended to exercise its audit rights under the MSA ("Audit Notice"). Leoni Decl. (ECF No. 55-4), Ex. A. On July 15, 2022, Novotech filed its Complaint. ECF No. 1. SureClinical filed an answer and counterclaim on August 12, 2022. ECF 8. In its later amended counterclaim, SureClinical alleges that Novotech granted unauthorized access to the Platform to thousands of unlicensed users. ECF 12 at 17. Novotech's Answer to the amended counterclaim denies liability and asserts several affirmative defenses, including a defense that all access to the Platform that Novotech granted was authorized by and within the scope of the license granted by the MSA. ECF 16 at 18.

SureClinical moved for a preliminary injunction on August 31, 2022, asking the court to order Novotech to comply with the Audit Notice on SureClinical's terms. ECF No. 13. On December 5, 2022, U.S. District Judge John A. Mendez granted SureClinical's motion for preliminary injunction. ECF No. 30. The court also stayed this action for sixty days pending completion of the MKA audit. Id. On January 6, 2023, SureClinical filed a Motion for Issuance of Order to Show Cause why Novotech Should Not be Held In Contempt And Sanctioned For Violation of Preliminary Injunction, arguing Novotech had not complied with the Court's Order of December 5, 2022, related to the audit provision. ECF No. 33. On January 18, 2023, Novotech opposed that motion and filed a separate Motion for Clarification and/or Amendment of that December 5th Order ("Motion to Amend"). ECF Nos. 39, 40.

On January 20, 2023, Judge Mendez issued an order granting Novotech's Motion to Amend, amending the Court's December 5 Order granting SureClinical's preliminary injunction motion, extending the stay by 30 days, and "den[ying] as moot" SureClinical's motion of January 6. ECF No. 41. The January 20 Order stated in pertinent part as follows:

> 3. Novotech is required to produce the documents identified in the July 14, 2022 letter from Miller Kaplan to Novotech [the Audit Notice], specifically items one through eleven, within thirty days of this amended order. Novotech's production should include, but is not limited to (1) the contracts between Novotech and the third-party users to whom Novotech granted access to SureClinical's platform and (2) the associated financial records related to the third-party usage of SureClinical's platform.
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> 4. Novotech is required to fully cooperate with Miller Kaplan's follow-up requests for information, if any.
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> 5. If Novotech cannot produce particular documents requested by Miller Kaplan by the end of the stay, it must provide a list of the documents at issue to SureClinical along with an explanation as to why the documents cannot be produced. If SureClinical believes that the lack of production is not in good faith, SureClinical is permitted to file a motion to compel production to the magistrate judge. The Court notes that Novotech has already had forty-five days to produce documents to Miller Kaplan.

Id. at 2.

On March 9, 2023, Judge Mendez lifted the litigation stay that had previously been extended. ECF No. 45. He ordered that "[f]rom this point forward, any disputes between the parties regarding discovery, *including the production of documents ordered by this Court on January 20, 2023* (ECF No. 41), shall be submitted to the assigned Magistrate Judge." ECF No. 45 at 2 (emphasis added). SureClinical submitted a motion to compel on March 31, 2023 before the undersigned (ECF No. 47) which was denied without prejudice for failure to meet and confer and for failure to file a joint statement. ECF No. 51. SureClinical then filed the renewed motion at bar. ECF No. 52 (joint statement at ECF No. 55).

As stated above, the motion asks the court to compel Novotech to give SureClinical's auditor direct access to Novotech's business records, to further grant access and cooperate in a forensic examination of its electronic systems and devices and media to the maximum extent necessary for a forensic examiner selected by SureClinical to determine whether or not Novotech

has destroyed, altered, or concealed records or information (including electronically-stored information and metadata) responsive or related to the audit, and to certify facts to the District Judge so that he can determine whether Novotech should be held in contempt for violating a court order. ECF No. 52 at 1-2.

II. Analysis

A. Legal Standard and Compliance with Audit Requirements

This is a dispute regarding compliance with an existing court order requiring Novotech to comply with the audit requirements specified in the parties' MSA. SureClinical argues that Novotech has not complied with three of its enumerated audit requests. The question before the court is whether Novotech has or has not sufficiently complied. The court notes that though this motion falls within the penumbra of discovery, it is not a typical motion to compel. While the District Judge ordered that compliance with the audit requirement be treated as a discovery dispute and the undersigned required the parties to meet and confer and file a joint statement in accordance with the local rules governing discovery (ECF No. 51), the legal standard applicable to motions to compel compliance with requests for production and interrogatories is not implicated because no interrogatories or requests for production have been issued.

Instead, the question before the court falls into another category often presented in the discovery context: whether the responding party has adequately complied with a court order. The solution, when a party fails to comply with a court order, is generally sanctions up to and potentially including an order of civil contempt. Civil contempt may be an appropriate sanction when a "party's disobedience to a specific and definite court order by failure to take all reasonable steps within the party's power to comply" is demonstrated by "clear and convincing evidence." In re Dual-Deck Video Cassette Recorder Antitrust Litig., 10 F.3d 693, 695 (9th Cir. 1993). "Substantial compliance with the court order is a defense to civil contempt, and is not vitiated by a few technical violations where every reasonable effort has been made to comply." Id. (internal citations omitted). Though an order of civil contempt is a final decision reserved to the District Judge (id.), the undersigned is guided by this standard in determining whether the court order has been violated and whether it should issue sanctions and/or certify facts regarding

civil contempt. It is clear, for example, that as the moving party SureClinical bears the burden of demonstrating a failure to comply.

In this case, the court order at issue requires Novotech "to produce the documents identified in the [Audit Notice], specifically items one through eleven, within thirty days of the date of this amended order," and that this "production should include, but is not limited to (1) the contracts between Novotech and the third-party users to whom Novotech granted access to SureClinical's platform and the associated financial records related to the third-party usage." ECF No. 41 at ¶ 3. While Novotech's general audit obligations are guided by the language of the MSA, present compliance must be evaluated in light of Judge Mendez's order that Novotech "fully cooperate with Miller Kaplan's follow-up requests for information." ECF No. 41 at 2. Judge Mendez has authorized the undersigned to compel production of documents pursuant to these orders. ECF No. 45 at 2. The disputed audit requests (6, 9 and 11) are addressed in turn below.

B. Audit Request 6

The request at issue addresses "Documentation with CRO's, Sponsors, Sites, consulting partners, reseller partners or others to support platform and clinical trial system licenses." ECF No. 55 at 12. Novotech responded as follows: "Novotech has provided contract documentation with Sponsors whose studies were hosted on the SureClinical platform during 2014-2022 in response to Supplemental MKA Letter, Category No. 1 on 16 February 2023. After reasonable and considerable search, and to the best of its knowledge, Novotech has no further documentation with CROs, Sponsors, Sites, consulting partners or others relating to the SureClinical platform or licenses. Novotech does not have any reseller partners relating to the SureClinical platform or licenses." Leoni Decl. (ECF No. 55-4), Ex. B ("Novotech Responses"). With respect to Novotech's third-party contract documentation, Novotech responds, "On January 18, 2023, Novotech sent MKA a 'List of Studies' showing 287 studies that had utilized the Platform. On February 17, 2023, Novotech produced approximately 1,700 documents consisting of contracts, change orders, and amendments between Novotech and its clients. On April 14, 2023, Novotech produced an additional 154 contractual documents." ECF No. 55 at 12.

SureClinical contends that MKA's review of the documents demonstrates Novotech's production is incomplete. ECF No. 55 at 12. Vince Leoni, the Miller Kaplan partner who is conducting the audit, has declared that the February 17 production does not include any documentation for many of the customers identified in the List of Studies, and that a significant percentage (one third of a random sample of twelve) of the contracts provided were unaccompanied by any invoices. Leoni Decl. (ECF No. 55-4) at ¶¶ 12, 16, 18, 24. Leoni further avers that budgets and invoices provided to date do not reconcile internally, and that other reconciliations cannot yet be attempted due to missing information. Id. at ¶ 19, 28. Moreover, SureClinical's own data regarding platform access suggests that unauthorized and undisclosed users may have accessed the platform under Novotech's auspices. Id. at ¶ 23.

To the extent that Novotech has produced only those documents it believes are relevant to an audit under the MSA, or only those documents that it has identified as related to use of the SureClinical platform, production is inadequate. The point of an audit is to test Novotech's representations as to use of the platform. Novotech has been ordered to respond to MKA's follow-up requests for information, which means providing documents that are requested or stating in writing what specific documents cannot be produced and why. In relation to Audit Request 6, Novotech must provide the documents and records that MKA seeks for its purposes, not those that Novotech thinks are relevant.

C. Audit Request 9

The audit request at issue reads "Access to invoice registers, sales invoices, and Order Forms for the Period." ECF No. 55 at 13. Novotech responded: "Novotech has provided invoices and Order Forms with SureClinical during 2014-2022 in response to MKA Letter, Category No. 4 and has provided a summary of all payments made to SureClinical during 2014-2022 pursuant to invoices and Order Forms with SureClinical in response to MKA Letter, Category No. 5." ECF No. 55 at 13. On March 14, MKA sent follow-up questions requesting "invoices and evidence of payment receipt" for specific Novotech customers. Leoni Decl. (ECF No. 55-4), Ex. C. Novotech responded: "Novotech invoices to its clients do not reference SureClinical charges and therefore we consider this request to be beyond the scope of the audit."

Id., Ex. D ("Novotech Follow-up Responses").

SureClinical argues that Novotech has not properly responded because, by limiting production to documents that reference SureClinical, it prevents Miller Kaplan from determining whether and to what extent Novotech granted third parties access to SureClinical's platform and what it received in exchange. ECF No. 55 at 18. Novotech asserts that is has complied with the audit request and that "(i) it does not charge or invoice its clients for use of or access to the SureClinical Platform; and (ii) the fees Novotech charges its clients for its professional services associated with the Platform (i.e., eTMF set up, maintenance and administration, technical regulatory compliance, and final reconciliation) – which are the same regardless of whether an eTMF was hosted on the Platform, some other platform, or no platform at all – are set forth in the budgets in Novotech's contracts with its clients." ECF No. 55 at 14.

The court agrees with SureClinical that the audit necessarily requires comprehensive records of transactions between Novotech and its customers during the relevant period. Limiting production to those documents that expressly reference SureClinical defeats the purpose of the audit. Novotech has been directly ordered to produce "associated financial records" and it must do so. Its relevance objections have twice been rejected by Judge Mendez and its obligation now is to provide what has been requested. Novotech's undue burden argument fails because (1) it comes too late and (2) it is not relevant to production pursuant to existing court orders.[1] Audits are meant to be comprehensive analyses of a company's finances and contractual relationships. Novotech must produce what MKA has requested.

D. Audit Request 11

Audit Request 11 seeks "Access to General Ledgers and/or audited financial statements for the Period for sales reconciliation purposes." ECF No. 55 at 14. Novotech responded that it "has provided a summary of all payments made to SureClinical during 2014-2022 pursuant to invoices and Order Forms with SureClinical derived from its General Ledger in response to MKA Letter, Category No. 5. Novotech has provided its consolidated audited financial statements for

[1] The proportionality requirement of the discovery rules does not apply here.

the period 2014-2021 on 16 February 2023." Id. SureClinical argues that the production of consolidated audited financial statements is unacceptable because the records show only transactions between Novotech and SureClinical, which is information SureClinical already has. ECF No. 55 at 14. SureClinical notes that the court's prior order specifically requires production of "financial records related to the third-party usage of the Platform." ECF 41. Novotech responds that, as it explained during meet and confer, audited financial statements at the entity level do not exist and it has produced all ledger entries associated with payments between Novotech and SureClinical. Id.

To the extent that Novotech has affirmatively represented that specific documents do not exist, e.g. "non-consolidated entity level audited financial statements," Hollway Decl. (ECF No. 55-3) at ¶ 52, SureClinical must accept the representation. However, for the reasons already stated, Novotech must produce the financial statements, general ledgers, and related invoices and other associated financial records that MKA has requested which do exist. Novotech may not withhold documents on the basis that they do not reference use of or access to the Platform.

E. Further Production Ordered

Within fourteen days of the date of this order, and subject to the parties' confidentiality agreement, Novotech shall provide to MKA all documents sought by MKA in relation to Audit Requests 6, 9 and 11. Production shall include, but is not limited to, extant documentation of the following items that MKA considers necessary and that the undersigned finds reasonably related to the scope of the audit and encompassed by Requests 6, 9 and 11:

- Sales reports to support company-wide sales by product at the contract and customer level for the Period. Such sales reports should include unique identifiers indicating whether studies utilized SureClinical Technology;
- Estimated project timelines;
- Change in scope log forms;
- Detailed account ledgers;
- Ledger listings showing, but not limited to:
    - Professional fees and expenses

- Investigator fees
- Upfront payments
- Pass through costs

- Any markups of fees and cost paid; and
- Companywide invoice registers, sales invoices, and Order Forms for the Period.

Novotech is not obliged to create financial statements or other documents that do not already exist nor, as explained below, to provide direct access to its record keeping systems. In the event that specific documents or categories of documents do not exist, a custodian must so state in writing. Any extant documents responsive to a request that are not produced must be specifically identified in writing with an explanation why they cannot be produced. ECF No. 41 at 2. As noted above, Novotech may not limits its production to clients or documents that it deems relevant to the audit.

F. A Forensic Examination is Not Warranted at this Time

SureClinical seeks direct inspection and a forensic examination of Novotech's records and electronic systems. This request is premature and will be denied without prejudice. The court trusts that Novotech will comply with the production obligations here ordered, providing all records sought by MKA so that the audit previously ordered can be completed without forensic examination.

G. Sanctions and Contempt

Although the court concludes that compliance with Judge Mendez's orders requires production of the business and financial records sought by SureClinical, it is not at all clear that Novotech has acted in bad faith. It appears that Novotech attempted to communicate with SureClinical and MKA to determine what specific additional documents were needed, at least as to some of the disputes here addressed. See Holloway Decl. (ECF No. 55-3). Novotech has taken positions as to the scope of the audit that, though here rejected by the undersigned, were perfectly arguable. Novotech's conduct therefore does not rise to the level of contempt and the undersigned declines the invitation to initiate contempt proceedings.

No sanctions will issue at this time.

Conclusion

The motion to compel (ECF No. 52) is GRANTED IN PART AND DENIED IN PART as set forth above. Each party shall bear its own costs. IT IS SO ORDERED.

DATED: July 31, 2023

ALLISON CLAIRE
UNITED STATES MAGISTRATE JUDGE